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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,458	03/12/2001	Michael P. Maher	AUROBIO.026DV3	8760

20995 7590 10/31/2003

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 10/31/2003

OKB

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,458

Applicant(s)

MAHER ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16 and 19-22, drawn to an assay apparatus, classified in class 204, subclass 403.01.
 - II. Claims 17 and 18, drawn to bottom panel of a multi-well plate; classified in class 422, subclass 99.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it doesn't require a bottom panel having conductive strips. The subcombination has separate utility such as by itself or with assays not utilizing a satellite electrode or not having a specified mean field intensity.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Eric Anderson on 10-13-2003 a provisional election was made with the right to traverse to prosecute the invention of group I, claims 1-16 and 19-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. The disclosure is objected to because of the following informalities: Page 1 has blank spaces for application information to be entered in. In addition, the reference to application numbers should be replaced, when possible, with appropriate patent or publication numbers.

8. Applicant also refers to pending applications on pp. 51, 52, 86, and 87. These should also be replaced, when possible, with appropriate patent or publication numbers. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-16 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1 and 22 have limitations drawn to having the electrodes provide an electric field that varies by less than a particular amount. However, these claims are drawn to apparatuses and apparatuses should be defined based on what the structure is and not what the structure does. In particular, whether the electrodes provide the specified mean field intensity depends at least in part on the characteristics of the voltages and currents applied to the electrodes as well as the characteristics of the fluid being placed in the well (e.g. conductive or charge carrying fluids would have different electric field properties than that of an insulating fluid). However, what voltage is applied to the electrodes and the fluid placed in the well are only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. The examiner recommends the applicant define the apparatus based on explicit recitation of structure drawn to what the device is and not on what it does.

12. In claim 9, there is no antecedent basis for "said plurality of wells".

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3, 5, 9, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Giaever et al (USP 5,187,096).

15. Giaever discloses an assay plate and electrode assembly comprising at least one sample well having electrodes placed therein (fig. 1 and 2). With respect to the limitations drawn to the mean field intensity (see 112 rejection above), that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

However, one of the electrodes 24 completely covers the bottom surface of well (fig. 2).

Because any electric field applied to that electrode 24 would extend across the entire electrode (and consequently the entire bottom surface of the well), it would be inherently capable of providing the claimed variance in mean field intensity when an electric field is applied to along that surface.

16. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Malin et al (USP 5,643,742).

17. Malin discloses an assay plate and electrode assembly that comprises at least one sample well 16 with electrodes positioned in those wells (fig. 4 and col. 4, lines 1-57). With respect to the limitations drawn to the mean field intensity (see 112 rejection above), that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

18. Claims 1, 3, 4, 9, 13 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold et al (USP 4,801,543).

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19. Arnold discloses an electrode assembly comprising a chamber (col. 7, lines 30-36) that would read on the term "well" giving the claim language its broadest reasonable interpretation. The well possesses more than two electrodes (4 or 8). With respect to the limitations drawn to the mean field intensity (see 112 rejection above), that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, the electrode arrangement of Arnold resembles the electrode arrangement of the instant invention (compare fig. 1 of Arnold with fig. 7-9 of the instant invention). Hence, it would appear that the electrodes of Arnold are inherently capable of satisfying the claimed mean field intensity variance of claim 1. With respect to the assembly being an assay device, that is also only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

20. With respect to claims 19-22 (those limitations not covered above), any number of the third through eight electrodes of Arnold would read on the applicant's broadly defined "satellite electrode" giving the claim language its broadest reasonable interpretation.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Giaever, Malin, or Arnold in view of Clark et al (USP 5,194,133)

24. The references individually set forth all the limitations of the claims, but did not explicitly recite the use of a material having high optical transparency, such as glass, for the assembly. However, glass is a conventional material that finds utility in the assay art for substrates. In particular, the use of glass is demonstrated by Clark (col. 2, lines 25-30). Glass inherently has a high optical transparency. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Clark for the assemblies of Giaever, Malin, or Arnold, because the substitution of one known material for another requires only routine skill in the art.

25. Claims 11, 12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaever et al.

26. Claims 10-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Malin et al or Arnold et al.

27. With respect to claims 10-12 (or 11 and 12 for Giaever), the references set forth all the limitations of the claim except for the provision of the set forth plurality of wells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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increase the number of wells to 96, greater than 96, or 384, because the mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Furthermore, more wells provide the ability to do more parallel analysis thereby increasing the throughput for a given assay device.

28. With respect to claims 14-16, the references do not explicitly set forth the spacings between the electrodes. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the set forth spacings, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing

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of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj K. Olsen', with a long horizontal flourish extending to the right.

Kaj K. Olsen
Patent Examiner
AU 1753
October 29, 2003